

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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JENNIFER PUCKETT,

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No. 21-1125V

Petitioner,

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Special Master Christian J. Moran

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v.

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Filed: June 3, 2024

SECRETARY OF HEALTH

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AND HUMAN SERVICES,

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Respondent.

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Laura J. Levenburg, Muller Brazil, Dresher, PA, for petitioner;

Nina Y. Ren, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION¹

Jennifer Puckett alleges that an influenza (“flu”) vaccine caused her to develop a cutaneous problem, Stevens-Johnson syndrome (often abbreviated “SJS”). Ms. Puckett was unable to support her claim with an opinion from an expert. Nonetheless, she maintains other evidence demonstrates her entitlement to compensation. The Secretary disputes Ms. Puckett’s claim that the flu vaccine injured her.

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

For the reasons explained below, Ms. Puckett is not entitled to compensation.

I. Background

Ms. Puckett was born in 1995. Exhibit 9 (damages affidavit) ¶ 1. She received flu vaccines on October 17, 2012 (intranasal), November 4, 2013 (intramuscular), and January 23, 2017 (intramuscular), and no issues were reported. Ex. 2 at 38; Ex. 3 at 453, 653.

Around the time of the allegedly causal vaccination, she worked at Jackson Hospital as a housekeeper. Exhibit 9 at ¶ 5.

On November 12, 2018, Ms. Puckett was tested for tuberculosis and tested negative. Exhibit 1 at 1. The test for tuberculosis is known as “PPD,” which stands for purified protein derivative. On this date, she also received a dose of the flu vaccine. Id.

Ms. Puckett sought care from the emergency department at Jackson Hospital on November 14, 2018. Exhibit 3 at 111. She reported developing a pruritic red papular rash for two days. She also informed medical personnel that she “just had a TB skin test and a flu shot.” Id. The emergency department physician stated: “[b]oth those sites [were] clear.” Id. at 112. She was admitted to the hospital with a concern for Stevens-Johnson syndrome.

She remained in Jackson Hospital for a few days. Ms. Puckett reported that, she had also been tested for tuberculosis “9 months ago” and did not have any issues. Exhibit 3 at 127.² During her stay, a doctor noted that she had hives “secondary to underlying drug reaction to possible flu shot versus PPD shot.” Id. As her disease progressed, she was transferred to the University of Alabama Hospital on November 17, 2018. Id. at 132, 385.

She stayed in the University of Alabama Hospital until December 12, 2018, when she was discharged to outpatient rehabilitation. Exhibit 4 at 211. The

² Ms. Puckett has not filed a record of any PPD test prior to the November 12, 2018 test. See Resp’t’s Rep. at 3 n.4 (requesting records). Without any records, her recollection of which test she underwent nine months prior is not afforded much weight.

doctors treated her for SJS and the diagnosis of SJS is not disputed in this litigation.

SJS occurs “in about one to three cases every million persons each year.” Exhibit 24 at e9405.³ It is a “life-threatening, severe cutaneous adverse reaction characterized by epidermal necrosis and systemic symptoms.” Exhibit 23 at 1. Photographs of Ms. Puckett display the extent of her lesions. Exhibits 10 and 15.

The course of Ms. Puckett’s case of SJS is not particularly relevant to the question in this litigation: did the flu vaccination, more likely than not, cause the SJS? Ms. Puckett’s treating doctors commented on potential causes:

Item	Date	Name & Specialty	Comment	Page within Exhibit 4
MET Provider Note	11/17/2018	Derek Russell, Medical Intensive Care Unit	“apparent SJS from vaccination”	755
Medical Intensive Care Unit (MICU) Impression and plan	11/18/2018	Neha Shantappa Teekappanavar (co-signed by Derek Russell, MICU)	“SJS vs viral exanthema (recent fevers).”	614
Dermatology Consult Assessment/Plan	11/18/2018	Craig Elmets, Dermatology	“inciting medication is unclear” but “do not favor PPD or influenza vaccine as causative currently.”	761

³ Jonathan Tong and Julie Chan, Stevens-Johnson Syndrome Due to Influenza Vaccination, 12 CUREUS e9405 (2020).

Item	Date	Name & Specialty	Comment	Page within Exhibit 4
MICU Attending Note	11/18/2018	Derek Russell, Medical Intensive Care Unit	"a large drug eruption attributed to flu vaccination."	631
Burns Progress Note	11/20/2018	Vanessa Miller, Specialty unknown	"Stevens Johnson Syndrome after receiving flu shot/PPD."	646
Inpatient Pain Service Consult	11/20/2018	Christopher Anderson (co-signed by Pankaj Desai, Anesthesia)	"SJS/TENS from flu vaccine or PPD test."	784
R4 TH-2 Accept Note	11/28/2018	Ali Said Al-Beshri (co-signed by James Willig, Infectious Diseases)	"6 day history of developing full body rash after receiving a flu shot and PPD . . . flu/PPD being most likely trigger."	619-21
Inpatient Pain Service Consult	12/2/2018	Brandon Seaver (co-signed by Pankaj Desai, Anesthesia)	"SJS/TENS from flu vaccine or PPD test"	801

After Ms. Puckett left University of Alabama Hospital, she continued to seek treatment for her SJS. Various doctors expressed views regarding the cause of the SJS.

Item	Date	Name & Specialty	Note	Cite
Assessment/Plan	12/18/2018	Constance Quinn, CRNP	“drug-induced Stevens-Johnson syndrome.”	Exhibit 2 at 33
Significant Medical Diagnoses and Conditions	1/31/2019	Christy Nichols, RN, Wound Center	“reaction to flu vaccine.”	Exhibit 3 at 28
Dermatology Clinic Notes	1/9/2019, 4/17/19	Patricia Mercado (co-signed by Joseph Purnell, Dermatology); repeated by Aubrey Pugh, CRNP, Dermatology.	“d/t ?? flu shot?”, “d/t flu shot vs idiopathic?”	Exhibit 4 at 37, 40-41, 128, 132
Allergies	6/29/2019	Rosa Bell, Neurology	“FLU VACCINATION reaction: STEVEN JOHNSON.”	Exhibit 6 at 7

II. Procedural History

The course of this litigation has been straightforward. Represented by Attorney Laura Levenberg, Ms. Puckett alleged the flu vaccine caused her to

develop Stevens-Johnson syndrome. Pet., filed Mar. 29, 2021. She periodically filed medical records, affidavits, and pictures.

The Secretary reviewed this material and recommended against an award of compensation. Resp't's Rep., filed Apr. 1, 2022. The Secretary identified various impediments. The Secretary maintained that the short interval (hours after vaccination) is too short to support an inference that the vaccine caused the SJS. Id. at 13-14. The Secretary commented that: "Many of petitioner's treating physicians mention both the flu vaccine and her PPD in a historical context." Id. at 14. Finally, the Secretary observed that none of the treating doctors presented a theory to explain how the flu vaccine can cause SJS in a few hours and that Ms. Puckett had not submitted a report from an expert. Id.

To facilitate the production of useful reports from experts, a set of instructions were proposed. Order, issued Sep. 13, 2013. When neither party interposed any objection, the instructions became final.

Ms. Puckett was first ordered to submit a report from an expert by December 13, 2022. Non-pdf order, issued Oct. 12, 2022. Ms. Puckett did not succeed and received additional time. Order, issued Dec. 9, 2022 (setting deadline of Feb. 7, 2023).

A status conference was held on February 13, 2023. Ms. Levenburg stated that she had not found an expert. Ms. Puckett, accordingly, was offered options, including presenting a report from an expert, seeking a new attorney, and/or arguing that she was entitled to compensation based upon the existing record. Order, issued Feb. 13, 2023.

Ms. Puckett took the third alternative by filing a motion for a ruling on the record. Pet'r's Mot., filed May 8, 2023. With this submission, Ms. Puckett also filed three articles about vaccines and SJS. Exhibits 23-25.

The Secretary responded, arguing that Ms. Puckett was not entitled to compensation. Resp't's Resp., filed July 6, 2023. The Secretary did not submit any exhibits.

Ms. Puckett did not reply to the Secretary within the time permitted by the Vaccine Rules. Thus, Ms. Puckett's case is ready for adjudication. Ms. Puckett requested a ruling that she was entitled to compensation based upon the record. She did not seek a hearing. See Pet'r's Br. The Secretary also did not request a

hearing. See Resp't's Br. Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When a petitioner, like Ms. Puckett, claims that a vaccine caused an injury not listed on the Vaccine Injury Table, such as SJS, the elements of a petitioner's case are well defined. A petitioner bears a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

To be awarded compensation, a petitioner must substantiate her claims with “medical records” or “medical opinion.” 42 U.S.C. § 300aa–13(a)(1). The lack of credible medical records or medical opinion can justify the dismissal of a case. Simeone v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 389, 396 (2023); Bloch v. Sec'y of Health & Hum. Servs., 126 Fed. Cl. 460, 467 (2016).

IV. Analysis

Ms. Puckett asserts that she meets the Althen prongs. Pet'r's Mot. at 7-11. Each element is discussed below, although the discussion is not in numeric order.

A. *Althen* Prong One

Ms. Puckett recognizes that Althen prong one requires her "to present a sound and reliable medical theory of causation demonstrating that the influenza vaccine could have caused Petitioner's Stevens-Johnson syndrome." Pet'r's Mot. at 7. Ms. Puckett argues, across about one-half a page, that she meets this standard because she submitted (1) case reports in which people received a vaccine and then developed SJS and (2) a study based upon the Vaccine Adverse Event Reporting System. Id. at 8. Ms. Puckett does not explicitly put forward a theory in this portion of her brief. See id. at 8.

In the context of litigation, case reports often do not receive much consideration as evidence of causation. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). Accordingly, the Calley article (exhibit 23) and the Tong article (exhibit 24) merit little weight.

Compared with the case reports, the third article could support an assertion that the flu vaccine can cause SJS. In this article, a group of authors, who worked for either the Centers for Disease Control or the Food and Drug Administration, examined reports of erythema multiforme, Stevens-Johnson syndrome and/or toxic epidermal necrolysis received by VAERS during 1999-2017. Exhibit 25 (Su) at pdf 1.⁴ The researchers discovered a two-year-old girl who received a flu vaccine, developed erythema multiforme, received another flu vaccine, and again developed erythema multiforme. Id. at 16. This pattern is known as "challenge-rechallenge." See Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1322 (Fed. Cir. 2006); see also Exhibit 25 at pdf 7. Challenge-rechallenge can constitute

⁴ Ms. Puckett submitted a manuscript version of this article. Therefore, citations to page numbers within the published volume are not available.

persuasive evidence of causation. See Capizzano, 440 F.3d at 1322; Stricker v. Sec’y of Health & Hum. Servs., No. 18-56V, 2024 WL 263189 at *25 (Fed. Cl. Spec. Mstr. Jan. 2, 2024), mot. for rev. denied, 2024 WL 1561699 (Fed. Cl. Mar. 27, 2024).

On the other hand, the value of this anecdote must be compared to the statistical analysis of the VAERS reports. Typically, analyses of VAERS reports have limited, if any, usefulness because in part the researchers are not aware of how many doses of a vaccine have been administered. See Flores v. Sec’y of Health & Hum. Servs., No. 10-489V, 2013 WL 5587390, at *12-13 (Fed. Cl. Spec. Mstr. Sep. 12, 2013) (“the VAERS system does not provide information as to the ‘background rate’ of a certain condition in a certain population”), mot. for rev. denied, 115 Fed. Cl. 157, 164 (2014), aff’d without op., 586 Fed. App’x 588 (Fed. Cir. 2014); Werderitsh v. Sec’y of Health & Hum. Servs., No. 99-319V, 2005 WL 3320041, at *15 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (denying motion for discovery for VAERS reports because, in part, petitioner did not have access to denominator data). But, for this article, the researchers attempted to estimate the number of administered doses by multiple the population by the vaccine coverage. Exhibit 25⁵ (Su) at pdf 4. Given the expertise and background of the authors as well as the lack of commentary from any retained expert, this methodology is accepted as minimally reliable. The researchers found “estimated median reporting rates of EM, SJS, and TEN to VAERS during 2010 through 2017 after influenza vaccine (all types) were ≤ 0.1 , < 0.1 , and < 0.1 per 1 million doses administered, respectively.” Id. at 6. This low incident rate seems to suggest that the flu vaccine is unlikely to cause Stevens-Johnson syndrome.

Although the incidence of a flu vaccination preceding Stevens-Johnson syndrome appears low, a petitioner in the Vaccine Program could prevail despite a lack of epidemiology. Thus, Ms. Puckett might have prevailed if she obtained a “medical opinion” in support of her claim. See 42 U.S.C. § 300aa–13(a)(1).⁶ The expert might have explained how theories mentioned in the medical articles could

⁵ John R. Su et al., Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis reported after vaccination, 1999-2017, 11 VACCINE 1746 (2020).

⁶ The “medical records” are discussed in the context of Althen prong two below.

explain how the flu vaccine can cause Stevens-Johnson syndrome. For example, the Calley article suggests that cytokines may activate cytotoxic T cells that lead to Stevens Johnson syndrome. Exhibit 23 (Calley) at 36-37.⁷ Information from the articles could have served to buttress the opinion from an expert but does not supplant the need for an expert. See LaLonde v. Sec’y of Health & Hum. Servs., 746 F.3d 1334, 1341 (Fed. Cir. 2014) (“petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard”); Caron v. Sec’y of Health & Hum. Servs., 136 Fed. Cl. 360, 388-89 (2018) (special master was not arbitrary in denying compensation when petitioner presented articles, but not a report from an expert or treater).

Overall, the material Ms. Puckett presented in arguing for prong one does not preponderate in her favor.

B. *Althen* Prong Three

The timing prong actually contains two parts. A petitioner must show the “timeframe for which it is medically acceptable to infer causation” and the onset of the disease occurred in this period. Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff’d without op., 503 F. App’x 952 (Fed. Cir. 2013).

A central part of Ms. Puckett’s argument is the analysis of VAERS reports conducted by Su and colleagues. See Pet’r’s Mot. at 11 (citing Exhibit 25 at 5). These researchers found “for cases of SJS with known time to onset, 71% described onset of symptoms within 3 days of vaccination.” Exhibit 25 (Su) at pdf 5. Approximately 20 percent occurred less than one day after the vaccination. Id. at pdf 12 (Table 1).

If it were found that the flu vaccine could cause Stevens-Johnson syndrome, the Su article would help Ms. Puckett establish that an interval from which an inference of causation could be appropriate might be less than one day. Presumably, if Su and colleagues thought that the latency was too quick, they would have rejected these reports from their analysis. See Mager v. Sec’y of

⁷ Ms. Puckett did not advance a theory based upon cytokines or T cells in her brief.

Health & Hum. Servs., 166 Fed. Cl. 414, 446-47 (2023) (ruling special master was not arbitrary in looking to a study based upon VAERS reports to find an appropriate temporal interval), appeal dismissed, 2023 WL 7318303 (Fed. Cir. Nov. 7, 2023).

Accordingly, Ms. Puckett has established prong three. This proof, however, does not necessarily entitle her to compensation. Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992) (“Temporal association is not sufficient, however, to establish causation in fact.”).

C. *Althen* Prong Two

With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

To establish that she has established a logical sequence of cause and effect, Ms. Puckett relies upon some statements from treating doctors. Pet’r’s Mot. at 8-10. The Secretary points to other statements from different doctors. Resp’t’s Resp. at 7-8. They are summarized in the two tables above.

In short, multiple doctors suggested that the cause of Ms. Puckett’s SJS was either the flu vaccine or the PPD. Ms. Puckett’s exposure to PPD constitutes a factor unrelated to the flu vaccine, which special masters may consider in weighing the evidence under prong two. See Winkler v. Sec’y of Health & Hum. Servs., 88 F.4th 958, 963 (Fed. Cir. 2023).

In arguing that Ms. Puckett had failed to meet her burden for Althen prong two, the Secretary emphasized the statements of a dermatologist: Ms. Puckett’s “dermatologists, who are the most relevant specialists in this case, did not conclude that the flu vaccine was the most likely cause of her condition.” Resp’t’s Resp. at 8, citing Exhibit 4 at 41, 132, 760-61. Because Ms. Puckett did not file a reply at all, she did not contest this argument. In any event, it is appropriate to focus upon the views of the doctor whose specialty most closely matches the condition at issue. See Spates v. Sec’y of Health & Hum. Servs., 76 Fed. Cl. 678, 684 (2007); Veryzer v. Sec’y of Health & Hum. Servs., No. 06-522V, 2011 WL 1935813, at *16-17 (Fed. Cl. Spec. Mstr. May 19, 2011) (declining to give much weight to statements of doctors who were opining outside their specialty), mot. for rev. denied, 100 Fed. Cl. 344, 354 (2011).

At the end of the day, Ms. Puckett received two substances, the purified protein derivative used to test for tuberculosis and the flu vaccine, on the same day on the premises of her employer. Each, conceivably, could have triggered a reaction leading to Stevens-Johnson syndrome. However, the Vaccine Program compensates people for injuries caused only by vaccines listed in the Table. As such, Ms. Puckett should have isolated the flu vaccine as the reason for her injury in causing her SJS. Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006). Ms. Puckett did not submit any evidence, such as an expert report, that persuasively distinguished the PPD test from the flu vaccine. As such, she is not entitled to compensation.

V. Conclusion

Ms. Puckett merits sympathy for enduring such a painful condition. But she has not presented persuasive evidence that the flu vaccine caused her SJS. Therefore, Ms. Puckett is not entitled to compensation.

The Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master